

Patent  
Attorney Docket: 491,920-029  
(prev 263/103)

### REMARKS

Applicant files this Rule 116 Amendment to the Office Action mailed July 11, 2003 in an attempt to resolve all outstanding issues, or failing that, to limit the number of issues for appeal. This Amendment is being filed within the two month window after the action, and an Advisory Action is requested.

Applicant appreciates the courtesy extended by the Examiner in the telephone interview today between the Examiner, the inventor, Dr. Ledergerber, and the undersigned. Applicant understands that the Examiner will be sending an interview summary later this week. As requested by the Examiner, this written response will address the various points still outstanding.

#### *Status of the Claims*

Applicant has cancelled claims 127-153 to conform to the Examiner's withdrawal of those claims from consideration. While Applicant believes that the newly added claims could be considered in this case, Applicant has cancelled those claims in this case in order to expedite prosecution.

#### *§ 112 Incorporation by Reference Issue*

The application as originally filed contained an explicit incorporation by reference of U.S. Patent No. 5,653,755 (as well as numerous others) which was the parent application to the continuation-in-part instant application. A copy of U.S. Patent No. 5,653,755 is provided herewith.

The Examiner has raised two procedural issues regarding the incorporation by reference. First, the Examiner noted that no printed copy of the patent was previously attached, nor was an affidavit or declaration filed. The undersigned however in the August 29, 2002 submission did explicitly state that the figures to be included herein correspond to Figures 4 and 10 of the parent

Patent  
Attorney Docket: 491,920-029  
(prev 263/103)

case, and that the text regarding those figures came from that parent case. As required by 37 C.F.R. § 10.18, as more fully set forth in MPEP § 410, the signing of that paper constituted a representation as to its factual accuracy. As such, Applicant would request that that document be treated as an affidavit or declaration. In the alternative, Applicant submits herewith a separate document regarding the point. Either way, Applicant requests that this technical rejection be withdrawn.

Second, the Examiner has suggested that the document itself incorporated "essential material" by reference. This rule has applicability where the matter to be incorporated by reference is not found in the primary document, but rather, requires resort to yet the next incorporation by reference to locate the subject matter. Such is not the case here. Applicant incorporates by reference *only one level back, namely, to U.S. Patent No. 5,653,755.*

Accordingly, the subject matter may properly be incorporated herein, and the amendments should be entered.

#### ***§ 112 Rejections Regarding Claim Language***

Claim 94 has been amended as suggested by the Examiner. Accordingly the claim now recites that the troughs lie in the same plane.

Claims 116-121 were rejected as indefinite. The Examiner correctly pointed out that these claims related to the combination of a sheet and a device. In order to focus on the sheet aspect as claimed, Applicant has cancelled Claims 116-121.

#### ***§ 103 Rejections***

The claims as now presented are clearly directed to a sheet-like structure. As noted, Claims 116-121 were cancelled as they were directed to the combination of a sheet with a device.

Patent  
Attorney Docket: 491,920-029  
(prev 263/103)

The claims now having been clearly directed to a sheet, must be compared with the prior art. The Examiner has now cited Netto. However, Netto does not disclose a sheet, but rather, a complete implant where the outer surface has no independent existence apart from the device. Even if Netto is viewed to disclose a sheet (which it does not), Netto clearly teaches that the material must be impermeable. The exterior material in Netto clearly must serve to contain the inner fluid, which may well be "a viscous fluid or a gelatin-like material". (Column 3, lines 2-4). In contrast, Applicant's claims require that the sheet be ePTFE. These materials are in no way equivalents. First and foremost, the fluid permeable nature of ePTFE, especially under pressure, would make the material wholly unsuitable for Netto's purpose. Indeed, the secondary reference relied upon by the Examiner (Mikulich et al.) recognizes this fact too. Mikulich et al. disclosed the use of ePTFE, but significantly do not teach its use for the layer interfacing with the body. Rather, a second, distinct layer of silicone elastomer is used. (Column 4, line 55 to Column 5, line 14). Indeed Mikulich expressly teaches that the external layer "prevents tissue in growth". In marked contrast, Applicant's invention would permit tissue in growth. Accordingly, the primary reference Netto contains no teaching of the claimed invention, and the secondary reference teaches away from the claimed invention.

As further support in this regard, Applicant submits the Declaration of Dr. Walter J. Ledergerber, M.D., the named inventor, under 37 C.F.R. § 1.132. This declaration is timely submitted under MPEP 716.01(A)(2) as it responds to the new ground of rejection in the Office Action mailed July 11, 2003.


Patent  
Attorney Docket: 491,920-029  
(prev 263/103)

Applicant respectfully requests that the claims be allowed without delay.

Respectfully submitted,

O'MELVENY & MYERS LLP

Dated: August 25, 2003

By:   
David B. Murphy  
Reg. No. 31,125  
Attorneys for Applicant

DBM/dnd

**34263**  
PATENT TRADEMARK OFFICE

O'Melveny & Myers LLP  
114 Pacifica, Suite 100  
Irvine, CA 92618-3315  
(949) 737-2900